

Proposal for standard contractual clauses for the procurement of artificial intelligence by public organisations version 0.9

Disclaimer

This is a draft document for discussion purposes only to collect initial feedback from stakeholders. This document is developed by Jeroen Naves (Pels Rijken). This is not an official EU document and it may not in any circumstances be regarded as reflecting an official position of the European Commission. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of this document. This document is still work-in-progress. No rights can be derived from this document.

VISIT...

LANZAROTE
Caliente.COM

Introductory remarks

These standard contractual clauses have been drafted for public organisations wishing to procure an AI System developed by an external supplier. These standard clauses are based on the standard clauses for the procurement of algorithmic systems developed by the City of Amsterdam in 2018 (<https://www.amsterdam.nl/innovatie/digitalisering-technologie/algoritmen-ai/contractual-terms-for-algorithms/>).

The standard contractual clauses presented in this draft are based to a large extent on the requirements and obligations for high-risk AI Systems included in the Title III of the proposal for a Regulation on artificial intelligence* ("AI Act"). This proposal is subject to ongoing negotiations so the clauses will need to be revised to take into account any changes made and fully align them with the final regulation adopted by the Council and the European Parliament.

Considering that the proposed AI Act is still under negotiations, public organisations that decide to use these conditions may do that on a voluntary basis assessing on a case-by-case basis whether the various sections of these standard contractual clauses are sufficient and proportionate for procuring a particular AI System. The standard contractual clauses target in particular AI systems classified as 'high-risk' within the meaning of Article 6 and listed in one of the areas covered by Annexes II and III of the proposed AI Act. For non-high risk AI the application of these requirements is not mandatory under the AI Act, but recommended to improve trustworthiness of AI applications procured by public organisations. Where appropriate and justified depending on the impact of the system on the individuals and the society, public organisations may also extend the application of these clauses to other algorithmic systems that may not be necessarily qualified as 'AI' to cover in addition simpler software rule-based systems, considering that their use in the public sector may also require in certain cases increased accountability, control and transparency.

The standard contractual clauses only contain provisions specific to AI Systems and on matters covered by the proposed AI Act, thus excluding other obligations or requirements that may arise under relevant applicable legislation such as the General Data Protection Regulation. Furthermore, these standard contractual clauses do not comprise a full contractual arrangement. For example, these standard contractual clauses do not contain any conditions concerning acceptance, payment, delivery times, applicable law or liability. The standard contractual clauses are drafted in such a way that they can be attached as a schedule to an agreement in which such matters have already been laid down.

* Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending certain union legislative acts, COM(2021)206 final.

Section A - Definitions**Article 1** Definitions

- 1.1. Capitalised terms used in these Clauses will have the meaning as defined in this article.
- **Agreement**: the entire agreement of which the Clauses, as a schedule, are an integral part;
 - **AI System**: the AI system(s) as referred to in **Annex A**, including any new versions thereof;
[optional] The parties may agree that these Clauses or parts thereof also apply to any algorithmic system regardless of whether the system is based on artificial intelligence or other digital technologies as described in Annex A.
 - **Clauses**: these standard contractual clauses for the procurement of artificial intelligence by public organisations;
 - **Data Sets**: the data set or data sets as described in **Annex B**, including any modifications or extensions thereof, as well as any other data sets created after the conclusion of the Agreement that are used in the context of the Agreement;
 - **Delivery**: the time at which the Supplier informs [NAME OF PUBLIC ORGANISATION] that the AI System satisfies all agreed conditions and is ready for use;
 - **Intended Purpose**: the use for which an AI System is intended by the Supplier, including the specific context and conditions of use, as specified in Annex B, the information supplied by the Supplier in the instructions for use, promotional or sales materials and statements, as well as in the technical documentation;
 - **Reasonably Foreseeable Misuse**: the use of the AI System in a way that is not in accordance with its Intended Purpose, but which may result from reasonably foreseeable human behaviour or interaction with other systems;
 - **Supplier**: the natural or legal person, public authority, agency or other body that supplies the AI System under its own trademark or name to [NAME OF PUBLIC ORGANISATION] pursuant to the Agreement.

Section B – Essential requirements in relation to the AI-system**Article 2** Risk management system

- 2.1. The Supplier ensures that, prior to the Delivery of the AI System, a risk management system shall be established, implemented and documented in relation to the AI System.
- 2.2. The risk management system shall at least comprise the following steps:

- a. identification and analysis of the known and foreseeable risks to health, safety and fundamental rights that are likely to arise in the light of the Intended Purpose of the AI System;
 - b. estimation and evaluation of the risks that may emerge when the AI System is used in accordance with its Intended Purpose and under conditions of Reasonably Foreseeable Misuse;
 - c. evaluation of other possibly arising risks;
 - d. adoption of suitable risk management measures in accordance with the provisions of the following paragraphs.
- 2.3. The risk management measures referred to in paragraph 2.3, point (d) shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications.
- 2.4. In identifying the most appropriate risk management measures referred to in paragraph 2.3, point (d), the following shall be ensured:
- a. elimination or reduction of risks as far as possible through adequate design and development;
 - b. where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;
 - c. provision of adequate information, in particular as regards the risks referred to in paragraph 2.3, point (b) of this article.
- 2.5. The Supplier ensures that, prior to the Delivery of the AI System, the AI System is tested in order to verify whether the AI System complies with the Clauses and whether the risk management measures referred to in paragraph 2.3, point (d) are effective in light of the Intended Purpose. If requested by the Public Organisation, the Supplier is obligated to test the AI System in the environment of [NAME OF PUBLIC ORGANISATION].
- 2.6. All risks identified, measures taken and tests performed in the context of compliance with this article will be documented by the Supplier. The Supplier must make these documents available to [NAME OF PUBLIC ORGANISATION] at the time of Delivery. The Supplier must update this documentation at least with every important change made to the AI System during its lifecycle, and subsequently make it available to [NAME OF PUBLIC ORGANISATION].

Article 3 < for AI Systems which make use of techniques involving the training of models with data/for other systems applicable only as relevant>
Data and data governance

- 3.1. The Supplier ensures that the Data Sets used in the development of the AI System, including training, validation and testing, shall be subject to appropriate data governance and management practices. Those practices shall concern in particular:
- a. the relevant design choices;
 - b. data collection;

- c. relevant data preparation for processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;
 - d. the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;
 - e. a prior assessment of the availability, quantity and suitability of the Data Sets that are needed;
 - f. examination in view of possible biases;
 - g. the identification of any possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.
- 3.2. The Supplier ensures that the Data Sets used in the development of the AI System, to the extent that it is possible with the current state of art, are relevant, representative, free of errors and complete. The Data Sets have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the AI System is intended to be used. These characteristics of the Data Sets may be met at the level of individual data sets or a combination thereof.
- 3.3. The Supplier ensures that the Data Sets used in the development of the AI System take into account, to the extent required by the Intended Purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the AI System is intended to be used.
- 3.4. The obligations under this article apply not only to the development of the AI System prior to Delivery, but also to any use of Data Sets at any other time during the term of the Agreement.

Article 4 Technical documentation and instructions for use

- 4.1. The Delivery of the AI System by the Supplier includes the handover of the technical documentation and instructions for use.
- 4.2. The technical documentation must be drawn in a way that allows to demonstrate and provide with the necessary information to assess the compliance of the AI System with the provisions of the requirements set in these Clauses and at least satisfy the conditions described in **Annex C**.
- 4.3. The instructions for use shall include concise, complete, correct and clear information that is relevant, accessible and comprehensible to [NAME OF PUBLIC ORGANISATION]. The instructions for use must at least satisfy the conditions described in **Annex D**.
- 4.4. **<optional>** The technical documentation and instructions for use must be drawn up in English.
- 4.5. **<optional>** [NAME OF PUBLIC ORGANISATION] has the right to make copies of the technical documentation and instructions for use to the extent necessary for internal use within the organisation of [NAME OF PUBLIC ORGANISATION], without prejudice to the provisions of article 6.

Article 5 Record-keeping

- 5.1. The Supplier ensures that the AI System shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the AI System is operating. Those logging capabilities shall conform to recognised standards or common specifications.
- 5.2. The logging capabilities shall ensure a level of traceability of the AI System's functioning throughout its lifecycle that is appropriate to the Intended Purpose of the system.

Article 6 Transparency

- 6.1. The Supplier ensures that the AI System shall be designed and developed in such a way to ensure that the operation of the AI System is sufficiently transparent to enable [NAME OF PUBLIC ORGANISATION] to interpret the system's output and use it appropriately.
- 6.2. **<optional>** During the term of the Agreement, the Supplier is obliged to assist [NAME OF PUBLIC ORGANISATION] at [NAME OF PUBLIC ORGANISATION]'s first request to explain on an individual level how the AI System arrived at a particular decision or outcome. In any event, this will include a clear indication of the key factors that led the AI System to arrive at a particular result and the changes to the input that must be made in order for it to arrive at a different outcome.
- 6.3. **<optional>** The obligation as described in article 6.2 comprises in any event the provision to [NAME OF PUBLIC ORGANISATION] of all the technical and other information required in order to explain how the AI System arrived at a particular decision or outcome and to offer the other party and any other interested parties the opportunity to verify the way in which the AI System arrived at a particular decision or outcome. The Supplier hereby grants the [NAME OF PUBLIC ORGANISATION] the right to use, share and disclose this information, if and to the extent necessary to inform natural persons about the functioning of the AI System and/or in any legal proceedings.
- 6.4. **<optional>** Without prejudice to Article 4, the obligations referred to in article 6.2 and article 6.3 include the source code of the AI System, the technical specifications used in developing the AI System, the Data Sets, technical information on how the Data Sets used in developing the AI System were obtained and edited, information on the method of development used and the development process undertaken, substantiation of the choice for a particular model and its parameters, and information on the performance of the AI System.

Article 7 Human oversight

- 7.1. The Supplier ensures that the AI System shall be designed and developed in such a way, including with appropriate human-machine interface tools, that it can be effectively overseen by natural persons.
- 7.2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when the AI System is used in accordance with its Intended Purpose or under conditions of Reasonably Foreseeable Misuse, in particular when such risks persist notwithstanding the application of other requirements set out in these Clauses.
- 7.3. The Supplier ensures that, prior to the Delivery, appropriate measures shall be embedded in the AI System and taken to ensure human oversight. These measures, which could include inter alia training of employees of PUBLIC ORGANISATION, shall enable the individuals to whom human oversight is assigned to do the following, as appropriate to the circumstances:
 - a. fully understand the capacities and limitations of the AI System and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;
 - b. remain aware of the possible tendency of automatically relying or over-relying on the output produced by the AI System ('automation bias'), in particular if the AI System is used to provide information or recommendations for decisions to be taken by natural persons;
 - c. be able to correctly interpret the AI System's output, taking into account in particular the characteristics of the system and the interpretation tools and methods available;
 - d. be able to decide, in any particular situation, not to use the AI System or otherwise disregard, override or reverse the output of the AI System;
 - e. be able to intervene on the operation of the AI System or interrupt the system through a "stop" button or a similar procedure.

Article 8 Accuracy, robustness and cybersecurity

- 8.1. The Supplier ensures that the AI System shall be designed and developed in such a way that it achieves, in the light of the Intended Purpose, an appropriate level of accuracy, robustness and cybersecurity, and performs consistently in those respects throughout its lifecycle.
- 8.2. The levels of accuracy and the relevant accuracy metrics of the AI System shall be declared in the accompanying instructions of use.
- 8.3. The Supplier ensures that the AI System shall be resilient as regards errors, faults or inconsistencies that may occur within the system or the environment

in which the system operates, in particular due to their interaction with natural persons or other systems.

- 8.4. The AI System shall be resilient as regards attempts by unauthorised third parties to alter their use or performance by exploiting the system's vulnerabilities.

The technical solutions to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Section C – Obligations of the Supplier in relation to the AI System

Article 9 Compliance with Section B

- 9.1. The Supplier must ensure that the AI System shall comply with the requirements established in Section B of these Clauses.
- 9.2. The Intended Purpose and the risk management system referred to in article 2 shall be taken into account when ensuring compliance with those requirements.

Article 10 **<optional for non-high-risk AI systems>** Quality management system

- 10.1. The Supplier shall put a quality management system in place that ensures compliance with these Clauses. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:
- a. a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the AI System;
 - b. techniques, procedures and systematic actions to be used for the design, design control and design verification of the AI System;
 - c. techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the AI System;
 - d. examination, test and validation procedures to be carried out before, during and after the development of the AI System, and the frequency with which they have to be carried out;
 - e. technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the AI System complies with the requirements set out in Section B of these Clauses;
 - f. systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration,

data mining, data aggregation, data retention and any other operation regarding the data that is performed before the Delivery of the AI System;

- g. the risk management system referred to in article 2;
 - h. the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with article 14;
 - i. procedures related to the reporting of serious incidents and of malfunctioning;
 - j. the handling of communication with national competent authorities, competent authorities, including sectoral ones, providing or supporting the access to data, notified bodies, other operators, customers or other interested parties;
 - k. systems and procedures for record keeping of all relevant documentation and information;
 - l. resource management, including security of supply related measures;
 - m. an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph.
- 10.2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the Supplier's organisation.

Article 11 **<optional for non-high-risk AI systems>** Conformity assessment

- 11.1. The Supplier shall ensure that the AI System undergoes the following conformity assessment procedure prior to the Delivery of the AI System:
- a. The Supplier verifies that the established quality management system is in compliance with the requirements of article 10.
 - b. The Supplier examines the information contained in the technical documentation in order to assess the compliance of the AI System with the relevant essential requirements set out in Section B of these Clauses.
 - c. The Supplier also verifies that the design and development process of the AI System and its post-market monitoring as referred to in article 14 is consistent with the technical documentation.
- 11.2. The Supplier ensures that the AI System shall undergo a new conformity assessment procedure whenever the AI System is substantially modified by the Supplier during the term of the Agreement. Substantial modification takes place in case of a change to the AI system following its placing on the market or putting into service which affects the compliance of the AI system with the requirements set out in Section B or results in a modification to the intended purpose for which the AI system has been assessed.

Article 12 Automatically generated logs

The Supplier shall keep the logs automatically generated by the AI System, to the extent such logs are under its control based on the Agreement. The logs shall be kept for a period that is appropriate in the light of the Intended Purpose and applicable law.

Article 13 Corrective actions

If the Supplier considers or has reason to consider that the AI system is not in conformity with these Clauses it shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. The Supplier shall inform the [NAME OF PUBLIC ORGANISATION] accordingly.

Article 14 **<optional for non-high-risk AI systems>** Post-market monitoring

- 14.1. The Supplier shall establish and document a post-market monitoring system in a manner that is proportionate to the nature of the artificial intelligence technologies and the risks of the AI System.
- 14.2. The post-market monitoring system shall collect, document and analyse relevant data when provided by [NAME OF PUBLIC ORGANISATION] or their users or collected through other sources on the performance of the AI System throughout its lifetime. This post-market monitoring system must allow the Supplier to evaluate the continuous compliance of the AI System with the requirements set out in these Clauses.
- 14.3. The post-market monitoring system shall be based on a post-market monitoring plan. The post-market monitoring plan shall be part of the technical documentation referred to in article 4.

Section D – Rights to use the AI System and the Data SetsArticle 15 **<optional>** Rights to use the AI System

- 15.1. The use of the AI System is subject to the provisions of the Agreement that pertain to intellectual property rights and licences.
- 15.2. If and to the extent that the Agreement does not contain any conditions on intellectual property rights and licences, the Supplier will grant the [NAME OF PUBLIC ORGANISATION] a non-exclusive, irrevocable right to use the AI System for the term of the Agreement.
- 15.3. This right to use the AI System includes, in any event, the following (for which the [NAME OF PUBLIC ORGANISATION] does not owe any additional fee):
 - a. the right to use all functionalities of the AI System;

- b. the right to make, save and regularly test copies of the AI System and keep them on hot standby for the purposes of disaster recovery;
 - c. the right to use the AI System for testing and development purposes;
 - d. the right to use the AI System without any limitation or restraint in terms of place and hardware, including its use by third parties on behalf of the [NAME OF PUBLIC ORGANISATION].
- 15.4. The [NAME OF PUBLIC ORGANISATION] may make and use copies of the AI System as often as it considers necessary for the purpose of its operational activities. If it does so and consequently owes an additional payment to the Supplier, it will immediately notify the Supplier accordingly. The [NAME OF PUBLIC ORGANISATION] may not remove any notices of ownership and copyright when reproducing the AI System.

Article 16 **<optional>** Rights to the Data Sets

- 16.1. All rights, including any intellectual property right, relating to the Data Sets to be provided by [NAME OF PUBLIC ORGANISATION] to the Supplier under the Agreement will accrue to [NAME OF PUBLIC ORGANISATION]. The Supplier will not be entitled to use such Data Sets for any purpose other than the performance of the Agreement. On first request of [NAME OF PUBLIC ORGANISATION], the Supplier will destroy such Data Sets and/or hand over the Data Sets to [NAME OF PUBLIC ORGANISATION], to be designated by [NAME OF PUBLIC ORGANISATION].
- 16.2. All rights relating to the Data Sets to be created or collected in the course of performance of the Agreement will accrue to [NAME OF PUBLIC ORGANISATION]. Unless the parties agree otherwise, the Supplier will not be entitled to use such data for any purpose other than the performance of the Agreement. If [NAME OF PUBLIC ORGANISATION] so demands, the Supplier will destroy such data and/or hand over the data to [NAME OF PUBLIC ORGANISATION], to be designated by [NAME OF PUBLIC ORGANISATION].
- 16.3. The Data Sets will be handed over to [NAME OF PUBLIC ORGANISATION] by the Supplier in a common file format to be designated by [NAME OF PUBLIC ORGANISATION]. If converting the data to the file format desired by [NAME OF PUBLIC ORGANISATION] requires the Supplier to perform additional work, [NAME OF PUBLIC ORGANISATION] will pay the Supplier a reasonable fee for that work. In no event will a dispute about the amount of the fee to be paid by [NAME OF PUBLIC ORGANISATION] give the Supplier the right to suspend its obligations under these Clauses.
- 16.4. If [NAME OF PUBLIC ORGANISATION] so demands, the Supplier will provide evidence of the destruction of the Data Sets.

Section E – AI register and audit**Article 17** **<optional>** AI register

- 17.1. At the [NAME OF PUBLIC ORGANISATION]'s first request, the Supplier will provide [NAME OF PUBLIC ORGANISATION] with the most recent version of the information described in Annex C and Annex D.
- 17.2. [NAME OF PUBLIC ORGANISATION] will be entitled to share the information described in article 17.1 with third parties and to disclose it, for example in a register for AI Systems.
- 17.3. If [NAME OF PUBLIC ORGANISATION] so demands, the Supplier will assist [NAME OF PUBLIC ORGANISATION] in completing a register, for example a register for AI Systems.

Article 18 **<optional>** Audit

- 18.1. The Supplier is obliged to cooperate in an audit or other type of inspection to be carried out by or on behalf of [NAME OF PUBLIC ORGANISATION] to assess whether the Supplier complies with its obligations laid down in these Clauses at all times. Such cooperation will include providing all information required by [NAME OF PUBLIC ORGANISATION], providing an insight into the risk management system implemented, making Supplier staff available for interviews and providing access to the locations of the Supplier.
- 18.2. [NAME OF PUBLIC ORGANISATION] will prepare, or cause the preparation of, a report in which the conclusions of the audit are recorded. In the report, [NAME OF PUBLIC ORGANISATION] will record the extent to which the Supplier complies with the obligations under the Agreement. If [NAME OF PUBLIC ORGANISATION] establishes that the Supplier does not comply with the obligations under this article, the Supplier will be obliged to remedy the defects identified by [NAME OF PUBLIC ORGANISATION] within the reasonable term set by [NAME OF PUBLIC ORGANISATION] in the report. If the Supplier fails to remedy the defects identified by [NAME OF PUBLIC ORGANISATION] within the term set in the report for remedying such defects, the Supplier will be in default by operation of law.
- 18.3. [NAME OF PUBLIC ORGANISATION] will be entitled to publish the conclusions of the report referred to in article 18.2.
- 18.4. [NAME OF PUBLIC ORGANISATION] will be entitled to perform, or cause the performance of, an audit once per calendar year.

- 18.5. [NAME OF PUBLIC ORGANISATION] may decide to have all or part of the audit performed by an independent auditor.
- 18.6. The costs of the auditor to be engaged by [NAME OF PUBLIC ORGANISATION], if any, will be paid by [NAME OF PUBLIC ORGANISATION]. [NAME OF PUBLIC ORGANISATION] will pay the Supplier a reasonable fee for any costs to be incurred by the Supplier in the context of the audit. In no event will a dispute about the amount of such fee give the Supplier the right to suspend its obligations under these Clauses. No such fee will be owed by [NAME OF PUBLIC ORGANISATION] if the audit reveals that the Supplier has failed to perform its obligations under these Clauses.

Section F – Costs**Article 19 <optional> Costs**

Unless agreed otherwise between the parties or expressly provided otherwise in these Clauses, no additional fee will be owed to the Supplier by [NAME OF PUBLIC ORGANISATION] in consideration of the work ensuing from these Clauses.

Annex A – The AI System

Within the scope of these clauses are all systems or components of systems provided by the Supplier to [NAME OF PUBLIC ORGANISATION] under the Agreement that meet the following definition:

“software that is developed with one or more of the techniques and approaches listed below and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

- (a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
- (b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;
- (c) Statistical approaches, Bayesian estimation, search and optimization methods.”

<Optional> In addition to the systems that fall within the scope of the aforementioned definition of an AI system, also the algorithmic systems or components of systems described below fall within the scope of the Clauses:

Please provide a description of the system. This can also be an algorithmic system that does not qualify as an AI System under the AI Act.

Annex B - The Data Sets and the Intended Purpose

Data Sets

Please provide a description of the Data Sets used for the training (if applicable), validation and testing of the AI System.

Intended Purpose

Please provide a description of the use for which the AI System is intended.

DRAFT

Annex C Technical documentation

The technical documentation shall contain at least the following information, as applicable to the relevant AI System:

1. a general description of the AI System including:
 - 1.1. its intended purpose, the person/s developing the system the date and the version of the system;
 - 1.2. how the AI System interacts or can be used to interact with hardware or software that is not part of the AI System itself, where applicable;
 - 1.3. the versions of relevant software or firmware and any requirement related to version update;
 - 1.4. the description of all forms in which the AI System is placed on the market or put into service;
 - 1.5. the description of hardware on which the AI System is intended to run;
 - 1.6. where the AI System is a component of products, photographs or illustrations showing external features, marking and internal layout of those products;
 - 1.7. instructions of use for the [NAME OF PUBLIC ORGANISATION] and, where applicable installation instructions.
2. a detailed description of the elements of the AI System and of the process for its development, including:
 - 2.1. the methods and steps performed for the development of the AI System, including, where relevant, recourse to pre-trained systems or tools provided by third parties and how these have been used, integrated or modified by the Supplier;
 - 2.2. the design specifications of the system, namely the general logic of the AI System and of the algorithms; the key design choices including the rationale and assumptions made, also with regard to persons or groups of persons on which the system is intended to be used; the main classification choices; what the system is designed to optimise for and the relevance of the different parameters; the decisions about any possible trade-off made regarding the technical solutions adopted to comply with the requirements set out in these Clauses;
 - 2.3. the description of the system architecture explaining how software components build on or feed into each other and integrate into the overall processing; the computational resources used to develop, train, test and validate the AI System;

- 2.4. where relevant, the data requirements in terms of datasheets describing the training methodologies and techniques and the training data sets used, including information about the provenance of those data sets, their scope and main characteristics; how the data was obtained and selected; labelling procedures (e.g. for supervised learning), data cleaning methodologies (e.g. outliers detection);
 - 2.5. assessment of the human oversight measures needed in accordance with article 7, including an assessment of the technical measures needed to facilitate the interpretation of the outputs of the AI System by [NAME OF PUBLIC ORGANISATION], in accordance with Annex D (4);
 - 2.6. where applicable, a detailed description of pre-determined changes to the AI System and its performance, together with all the relevant information related to the technical solutions adopted to ensure continuous compliance of the AI System with the relevant requirements set out in these Clauses;
 - 2.7. the validation and testing procedures used, including information about the validation and testing data used and their main characteristics; metrics used to measure accuracy, robustness, cybersecurity and compliance with other relevant requirements set out in these Clauses as well as potentially discriminatory impacts; test logs and all test reports dated and signed by the responsible persons, including with regard to pre-determined changes as referred to under point 2.6.
3. Detailed information about the monitoring, functioning and control of the AI System, in particular with regard to: its capabilities and limitations in performance, including the degrees of accuracy for specific persons or groups of persons on which the system is intended to be used and the overall expected level of accuracy in relation to its intended purpose; the foreseeable unintended outcomes and sources of risks to health and safety, fundamental rights and discrimination in view of the intended purpose of the AI System; the human oversight measures needed in accordance with article 7, including the technical measures put in place to facilitate the interpretation of the outputs of the AI System by [NAME OF PUBLIC ORGANISATION]; specifications on input data, as appropriate;
4. a detailed description of the risk management system in accordance with article 2;
5. a description of any change made to the system through its lifecycle.

Annex D Instructions for use

The instructions for use shall contain at least the following information, as applicable to the AI System:

1. the identity and the contact details of the Supplier and, where applicable, of its authorised representative;
2. the characteristics, capabilities and limitations of performance of the AI System, including:
 - 2.1. its intended purpose;
 - 2.2. the level of accuracy, robustness and cybersecurity referred to in article 8 against which the AI System has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;
 - 2.3. any known or foreseeable circumstance, related to the use of the AI System in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;
 - 2.4. its performance as regards the persons or groups of persons on which the system is intended to be used;
 - 2.5. when appropriate, specifications for the input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI System.
3. the changes to the AI System and its performance which have been pre-determined by the Supplier at the moment of the initial conformity assessment, if any;
4. the human oversight measures referred to in article 7, including the technical measures put in place to facilitate the interpretation of the outputs of the AI System by the [NAME OF PUBLIC ORGANISATION];
5. the expected lifetime of the AI System and any necessary maintenance and care measures to ensure the proper functioning of that AI System, including as regards software updates.